

Amendments to the Claims

Following is a complete set of claims as amended with this Response. This complete set of claims includes amended claims 27-33.

1. (Previously Amended) A method for controlling a patient's heart rate, comprising:

transvenously positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch;

positioning an atrial electrode in the patient's atrium;

detecting the patient's atrial rate; and

delivering stimulation pulses to the vagal electrode when a fast atrial rate is detected, the stimulation pulses being delivered at a level that reduces the atrial rate to a normal operating range.

2. (Original) The method of claim 1, wherein the delivering step comprises: adjusting the level of stimulation pulses so that the atrial rate decreases to a predetermined lower atrial rate.

3. (Original) The method of claim 2, wherein adjusting the level of stimulation pulses comprises:

adjusting the level of stimulation pulses so that the atrial rate decreases to within a normal range.

4. (Original) The method of claim 2, wherein adjusting the level of stimulation pulses comprises:

adjusting the level of stimulation pulses so that the atrial rate decreases to substantially half of the detected fast atrial rate.

5. (Original) The method of claim 2, wherein adjusting the level of stimulation pulses comprises:

adjusting at least one of amplitude, pulse width and frequency.

6. (Previously Amended) A method for controlling a patient's heart rate, comprising:

positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch;

positioning an atrial electrode in the patient's atrium;

detecting the patient's atrial rate; and

delivering stimulation pulses to the vagal electrode when a fast atrial rate is

detected, the stimulation pulses being delivered at a level that reduces the atrial rate to a normal operating range;

wherein the delivering step comprises adjusting the level of stimulation pulses so that the atrial rate decreases to a predetermined lower atrial rate;

wherein adjusting the level of stimulation pulses comprises adjusting at least one of amplitude, pulse width and frequency; and

wherein adjusting of the level of stimulation pulses further comprises:

testing a plurality of amplitude, pulse width and frequency combinations;

recording current drain for the plurality of amplitude, pulse width and frequency combinations;

determining at least one combination of amplitude, pulse width and frequency that reduces current drain; and

delivering the stimulation pulses to the vagal electrode at a level that reduces the atrial rate to the predetermined lower rate while reducing current drain.

7. (Previously Amended) A method for controlling a patient's heart rate, comprising:

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positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch;
positioning an atrial electrode in the patient's atrium;
detecting the patient's atrial rate; and
delivering stimulation pulses to the vagal electrode when a fast atrial rate is detected, the stimulation pulses being delivered at a level that reduces the atrial rate to a normal operating range;
wherein the delivering step comprises adjusting the level of stimulation pulses so that the atrial rate decreases to a predetermined lower atrial rate;
wherein adjusting the level of stimulation pulses comprises adjusting at least one of amplitude, pulse width and frequency; and
wherein adjusting of the level of stimulation pulses further comprises:
varying a plurality of amplitude, pulse width and frequency combinations to determine whether varying degrees of lower atrial rates can be achieved;
recording corresponding atrial rates for the plurality of amplitude, pulse width and frequency combinations; and
selecting a particular amplitude, pulse width and frequency combination that corresponds to the predetermined lower atrial rate.

8. (Original) The method of claim 2, further comprising:
positioning a ventricular electrode in the patient's ventricle;
monitoring A-V conduction intervals; and
wherein the delivering step comprises delivering stimulation pulses at a level that does not cause A-V dissociation.

9. (Original) The method of claim 8, wherein the adjusting step further comprises:

determining a plurality of operating parameter combinations that do not cause A-V dissociation, each combination including a stimulation pulse amplitude, frequency and pulse width;
recording the resultant heart rate reduction for each combination; and
wherein the delivering comprises delivering the stimulation pulses to the vagal electrode using the operating parameter combination that substantially achieves the predetermined lower atrial rate.

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10. (Original) The method of claim 8, wherein the adjusting of the level of stimulation pulses further comprises:

recording current drain for the plurality of operating parameter combinations that do not cause A-V dissociation; and
wherein the delivering comprises delivering the stimulation pulses to the vagal electrode using the operating parameter combination that reduces the atrial rate without A-V dissociation and reduces current drain.

11. (Original) The method of claim 1, further comprising:
periodically discontinuing delivering of the stimulation pulses to the vagal electrode;
testing to determine if the atrial rate has returned to a normal range;
disabling the delivery of the stimulation pulses to the vagal electrode when the atrial rate is in a normal range; and
continuing the delivery of the stimulation pulses to the vagal electrode when the fast atrial rate is still present.

12. (Previously Amended) A method for controlling a patient's heart rate, comprising:

positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch;

positioning an atrial electrode in the patient's atrium;

detecting the patient's atrial rate; and

delivering stimulation pulses to the vagal electrode when a fast atrial rate is

detected, the stimulation pulses being delivered at a level that reduces the atrial rate to a normal operating range;

wherein the positioning comprises positioning the vagal electrode in the right azygos vein.

13. (Original) The method of claim 12, wherein the positioning the vagal electrode in the right azygos vein comprises deploying an expandable vagal electrode configured to make contact with tissue proximate to the vagus nerve.

14. (Previously Amended) A method for controlling a patient's heart rate, comprising:

positioning a vagal electrode proximate to the patient's right vagus nerve near the patient's cardiac branch;

positioning an atrial electrode in the patient's atrium;

detecting the patient's atrial rate; and

delivering stimulation pulses to the vagal electrode when a fast atrial rate is

detected, the stimulation pulses being delivered at a level that reduces the atrial rate to a normal operating range;

wherein the positioning comprises positioning the vagal electrode in the Superior Vena Cava (SVC) near the right cardiac branch.

15. (Original) The method of claim 14, wherein the positioning the vagal electrode in the SVC comprises deploying an expandable vagal electrode configured to make contact with tissue proximate to the vagus nerve and the right cardiac branch.

16. (Original) An implantable stimulation lead for enhancing a patient's vagal tone, comprising:

a transvenous lead body having an insulating sheath surrounding at least one conductor, the at least one conductor being coupled to at least one proximal connector; and

an electrode portion, coupled to the conductor, configured to be positioned within a patient's azygos vein and dimensioned to make contact with tissue proximate to the cardiac branch of the right vagus nerve.

17. (Previously Amended) The implantable lead of claim 16, wherein the lead body comprises a preformed turn that orients the electrode portion into the patient's azygos vein.

18. (Original) The implantable lead of claim 16, wherein the lead body comprises a single-pass lead body having at least one electrode configured to be positioned in a desired chamber of the patient's heart, the single-pass lead body further comprising a side-arm that branches near, and directs the electrode portion into, the patient's azygos vein.

19. (Previously Amended) The implantable lead of claim 16, wherein the electrode portion comprises at least one electrode facing towards the patient's vagus nerve.

20. (Original) The implantable lead of claim 16, wherein:

the electrode portion comprises an expandable electrode that is dimensioned to expand and anchor against the azygos vein.

21. (Original) The implantable lead of claim 20, wherein:

the expandable electrode is one of a basket electrode, an umbrella-type electrode or spiral electrode.

22. (Original) The implantable lead of claim 16, further comprising:

a distal tail, coupled to a distal end of the electrode portion, that extends into the azygos vein to provide stabilization.

23. (Original) The implantable lead of claim 22, wherein the distal tail

comprises at least one of a hook, a tine, a spiral or a pre-formed bend capable of anchoring the distal tail in a desired position.

24. (Original) The apparatus of claim 16, wherein the lead body comprises a single-pass lead body having at least a second and a third electrode portion positionable within a first and second chamber of the patient's heart such that at least A-V synchrony can be monitored.

25. (Original) The apparatus of claim 16, wherein the lead body comprises a single-pass lead body having at least a second and a third electrode positionable within a first and second chamber of the patient's heart such that at least A-V synchrony can be maintained.

26. (Original) The apparatus of claim 16, wherein the lead body comprises a single-pass lead body having at least a second and a third electrode positionable proximate to a first and second chamber of the patient's left heart via the coronary sinus region such that at least A-V synchrony and left-sided stimulation therapy can be maintained.

27. (Currently Amended) An implantable ~~single-pass stimulation lead~~ cardiac stimulation system for controlling a patient's atrial rate, comprising:

a vagal module to determine operating parameters for vagal stimulation;

a transvenous lead body having an insulating sheath having first and second conductors, the first and second conductors being electrically isolated and respectively coupled to first and second proximal terminals, the second proximal terminal coupled to the vagal module;

an atrial electrode, coupled to the first conductor, and configured on the lead body so as to be capable of sensing atrial signals; and

an electrode portion, coupled to the second conductor and the vagal module, configured to be positioned within a patient's superior vena cava (SVC) and dimensioned to make contact with tissue proximate to the cardiac branch of the right vagus nerve, the electrode portion adapted to deliver stimulation pulses to the right vagus nerve to reduce the atrial rate.

28. (Currently Amended) The ~~implantable lead~~ system of claim 27, wherein the electrode portion comprises at least one electrode facing towards the patient's vagus nerve.

29. (Currently Amended) The ~~implantable lead~~ system of claim 27, wherein: the electrode portion comprises an expandable electrode that is dimensioned to expand and anchor against the azygos vein.

30. (Currently Amended) The ~~implantable lead~~ system of claim 29, wherein: the expandable electrode is one of a basket electrode, an umbrella-type electrode or spiral electrode.

31. (Currently Amended) The ~~apparatus~~ system of claim 27, wherein the ~~single-pass transvenous~~ lead body further comprises a ventricular electrode configured on the lead body so as to be capable of sensing ventricular signals such that at least A-V synchrony can be monitored.

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32. (Currently Amended) The ~~apparatus~~ system of claim 27, wherein the ~~single-pass transvenous~~ lead body further comprises a ventricular electrode configured on the lead body so as to be capable of sensing ventricular signals such that at least A-V synchrony can be maintained.

33. (Currently Amended) The ~~apparatus~~ system of claim 27, wherein the ~~single-pass transvenous~~ lead body further comprises a ventricular electrode configured on the lead body so as to be capable of sensing atrial and ventricular signals when implanted within the coronary sinus region such that at least A-V synchrony and left-sided stimulation therapy can be maintained.
